REMARKS

The present Amendment is in response to the Examiner's Office Action mailed August 1, 2001. Reconsideration of the application is respectfully requested in view of the above amendments to the Specification and drawings and the following remarks. For the Examiner's convenience and reference, Applicants' remarks are presented in the order in which the corresponding issues were raised in the Office Action.

I. Objection To The Specification

The Examiner objects to the Specification indicating several informalities. Applicants amend the Specification to address these informalities. Withdrawal of this objection in view of the above amendments is respectfully requested.

II. Objection To The Drawings

The Examiner objects to the Drawings because element 18 is not described in the Specification. Applicants amend the Specification to delete reference to element 18. Withdrawal of this objection in view of the above amendment is respectfully requested.

III. Anticipation Rejection

The Examiner rejects claim 1 as being anticipated under 35 USC 102(b) by Steffee. Claim 1 has been cancelled and new claims are presented. The Examiner will note that the new claims specify first and second anchor plates that are not attached to each other. By contrast, Steffee teaches a device where plates 12 and 14 are bonded to an elastomeric core. See Steffee, Col. 5, lines 54-55. Accordingly, for this and other reasons, Steffee does not anticipate Applicant's new claims. Withdrawal of this ground of rejection is therefore requested in view of the new claims.

IV. Obviousness-type Double Patenting Rejection

The Examiner rejects claim 1 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,113,638. Applicants submit a terminal disclaimer relative to this patent and request that the rejection be withdrawn in view of this submission.

CONCLUSION

Applicants earnestly believe that they are entitled to a letters patent, and respectfully solicit the Examiner to expedite prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned.

Respectfully submitted,

Date: Dec. 13, 2001

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Please amend the specification as follows:

In the Specification:

The paragraph on page 1, beginning on line 14, has been amended as follows:

The human spine is a flexible structure comprised of thirty-three vertebrae. Intervertebral discs separate and cushion adjacent vertebrae, and act as shock absorbers and allow bending between the vertebrae. An intervertebral disc comprises two major components: the nucleus pulposus and the annulus fibrosis. The nucleus pulposus is centrally located in the disc and occupies 25-40% of the disc's total cross-sectional area. The annulus fibrosis surrounds the nucleus pulposus and resist torsional and bending force applied to the disc. Vertebral end-plates separate the disc from the [vertebra] vertebrae on either side of the disc.

The paragraph on page 2, beginning on line 10, has been amended as follows:

To promote fusion or arthrodesis across the intradiscal space, intervertebral implants are used to support and fuse together adjacent vertebrae by posterior-fusion or anterior grafting. For example, surgical prosthetic [implant] implants for vertebrae described in US Patent No. 5,827,328 include rigid annular plugs that have ridged faces to engage adjacent vertebrae to resist displacement and allow ingrowth of blood capillaries and packing of bone graft. These annular implants are usually made of biocompatible carbon fiber reinforced polymers, or traditional orthopaedic implant materials such as nickel, chromium, cobalt, stainless steel or titanium. The individual implants are internally grooved and are stacked against each other to form a unit between the two adjacent vertebrae. One of the disadvantages of these interlocked implants is that, the implants may not be stable enough to withstand rotation and may lead to implant loosening and failure of the prosthesis.

The paragraph on page 5, beginning on line 14, has been amended as follows:

In yet another embodiment, the implantable device includes first and second anchor plates[, inserting including] . Inserting the intradiscal device includes positioning the first anchor plate adjacent a first of the adjacent vertebra and positioning the second anchor plate adjacent a second of the adjacent vertebra[, and causing including] . Causing the anchoring elements to be introduced into the vertebrae includes causing anchoring elements on the first anchor plate to be introduced into the first vertebra and causing anchoring elements on the second anchor plate to be introduced into the second vertebra.

The paragraph on page 9, beginning on line 12, has been amended as follow:

One embodiment of the invention is illustrated in Figure 1, showing a frontal view of an implantable device 10 inserted between two adjacent vertebrae L4 and L5. In this embodiment, the implantable device 10 includes a first anchor plate 12, a second anchor plate 14 and an intradiscal component 16. Each of the first and second anchor plates includes [a plate member 18 and] a plurality of anchoring elements 20 extending from a surface 11 of the [plate member 18] anchor plate. The anchoring elements 20 on each of the anchor plates 12 and 14 are introduced into vertebrae L4 and L5 through end plates E4 and E5 of vertebrae L4 and L5, respectively. This embodiment of the implantable device has a size approximating the intradiscal space between adjacent vertebrae. This device is particularly suitable for positioning via an anterior approach. Because intervertebral discs are located in front of the spine and anterior to the spinal cord 15, prosthetic operations such as disc replacement through an anterior approach eliminates the need to remove or retract nerve, thus reducing the risk of nerve injury.

The paragraph on page 9, beggining on line 28, has been amended as follows:

Alternatively, the implantable device according to the present invention may also be sized to a hemicycle or [hemioval] hemicircle. As illustrated in Figure 2, two hemioval implantable devices 30 and 32 can be used to approximate the intradiscal space and conform with the general outline perimeter of the vertebrae. Such an implantable device with a hemioval size allows better

access to the posterior portion of the spine when the devices are implanted through a posterior approach. For example, the first hemi- device 30 can be inserted into and fill in half of the intradiscal space without colliding with the spinal [core 15] cord, then followed by placing the second hemi- implantable device 32 to fill in the other half of the intradiscal space. Similar to the implantable device 10 illustrated in Figure 1, the anchoring elements on the hemi-implantable device are introduced into the end plate E4 and E5 of the vertebrae L4 and L5, respectively. Bone graft material or artificial disc can be put into the device for posterior-lateral fusion or rigid posterior instrumentation. Positioning the bone graft material between first and second anchor plates 12, 14 to attain fusion and prevent the anchor plates from being dislodged from the vertebrae.

The paragraph on page 12, beginning on line 14, has been amended as follows:

The materials used to construct the anchor plate and the implantable device are preferred to be able to endure the stresses and environment to which a vertebra implant is subjected. In addition, such materials should be biocompatible, and substantially chemically inert so as not to cause any detrimental effect to the patient in whom the device is implanted. The anchor plate and implantable device may be made of radiolucent material such as carbon fiber reinforced polymers known commercially as "Peek" (polyetherether ketone) or "Ultrapek" (polyether ketone, ether ketone, ketone), polycarbonate, polyprophylene, polyethylene and polysulfone plastics material filled with glass or carbon fibers, or traditional orthopaedic implant material such as nickel stainless steel, titanium alloy, heavy plastic polymer, ceramic, etc. One of ordinary skill in the art will recognize other suitable materials, for example, a cobalt-chromium alloy or a titanium alloy having 4% vanadium and [%] aluminum, ceramic material such as aluminium oxide and zirconium oxide. The surface 71 of the anchor plate 70 is preferred to be rough to potentiate bone ingrowth on the side of the plate contacting the end plate E4 of the vertebra L4, thereby strengthening the anchorage to the end plate. The surface 73 of the anchor plate 70 may be porous coated or coated with hydroxyapatite or bioactive proteins (e.g. bone morphogenic protein) to promote bone ingrowth.

The paragraph on page 17, beginning on line 1, has been amended as follows:

In yet another embodiment according to the method, the implantable device includes first and second anchor plates, inserting including positioning the first anchor plate adjacent a first of the adjacent vertebra and positioning the second anchor plate adjacent a second of the adjacent vertebra, and [causing] the anchoring elements to be introduced into the vertebrae including causing anchoring elements on the first anchor plate to be introduced into the first vertebra and causing anchoring elements on the second anchor plate to be introduced into the second vertebra.